OPERATION / SERVICE MANUAL

IQmark™
Digital Holter Recorder CF

MIDMARK®

Part Number: 3-100-1045 Revision G

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A Word of Thanks

Thank you for your purchase of the IQmark Digital Holter Recorder^{CF}. Midmark has used the latest microelectronic and computer software technology to develop a fast, efficient and accurate digital Holter system.

We believe you will be pleased with the user-friendly operation of our product and its results. As your partner in healthcare, we look forward to working with you in the coming years as we develop even more sophisticated diagnostic technology for the cardiopulmonary field. Your thoughts, questions and comments about our product are welcome.

CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

Physician's Responsibility

The results provided by IQmark Digital Holter Recorder^{CF} are for the exclusive use of licensed physicians or personnel under their direct supervision.

It is the responsibility of the physician to ensure proper administration of the test, making a diagnosis, obtaining expert opinions on the results and instituting the correct treatment.

Disclosures

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Precautions

Read the following to ensure the proper operation of the IQmark Digital Holter Recorder^{CF}:

1. Familiarize yourself thoroughly with the operational procedures of the IQmark Digital Holter Recorder^{CF} prior to use.
2. Disconnect the recorder from patients during defibrillation.
3. The recorder is not designed for sterile use.
4. The recorder is not intended for use with rechargeable batteries.
5. Instrument maintenance:
   - Keep the recorder away from splashing water.
   - Do not store or use the recorder where humidity, ventilation, direct sunlight or air containing dust, salt or sulfur might affect it.
   - Prevent the recorder from slipping and protect it from the possibility of vibration, shock or drop; be particularly careful during transport.
   - Do not store or use the recorder in a chemical storage area, or where gas is generated.
6. Preparation of the recorder prior to operation:
   - Verify proper recorder operation.
   - Check that cable connections are secure.
7. Precautions while using the recorder:
   - Avoid activities that could affect the quality of recorded signals. Do not sleep under an electric blanket.
   - Patients should not shower, take baths, use hot tubs or perform similar activities while wearing the recorder.
   - Keep the recorder and electrode sites dry while in use.
   - **Do not tamper with the recorder. Do not remove the flashcard or battery until the recording is complete.**
8. Precautions after using the recorder:
   - Remove the batteries and flashcard.
   - Download patient data to computer as soon as possible to preserve patient data.
   - Do not remove then reinstall batteries with the flashcard installed. Patient data will be lost.
   - Keep the recorder clean to ensure trouble-free operation during next use.
9. Perform routine inspection of the recorder and accessories.
10. Do not make any modifications to the recorder.

DANGER: Possible explosion hazard if used in the presence of flammable anesthetics.

CAUTION: Refer servicing to qualified service personnel.

I. General Information

Figure 1-1 The IQmark Digital Holter Recorder^{CF}

Description

The IQmark Digital Holter Recorder^{CF} is a lightweight, compact, digital Holter recorder designed for reliability and ease of use in ambulatory ECG applications. Because the digital design has no moving parts, the IQmark Digital Holter Recorder^{CF} records cleaner ECG quality and has lower maintenance cost when compared to tape-based Holter recorders.

A liquid crystal display (LCD) assists Holter technicians in the verification of proper patient hookup, eliminating the need for expensive test cable interfaces with EKG machines.

The IQmark Digital Holter Recorder^{CF} can be configured as a 7-lead/3-channel or 5-lead/3-channel recorder by changing the patient cable.

Data is conveniently stored on a reusable flashcard, eliminating the need for cassette tapes. Digital technology also eliminates tape-based variables such as tape-head frequency, speed variations, distortion and tape brand inconsistencies. The removal of these variables produces more accurate ST segment and RR interval readings.

A. Key Components

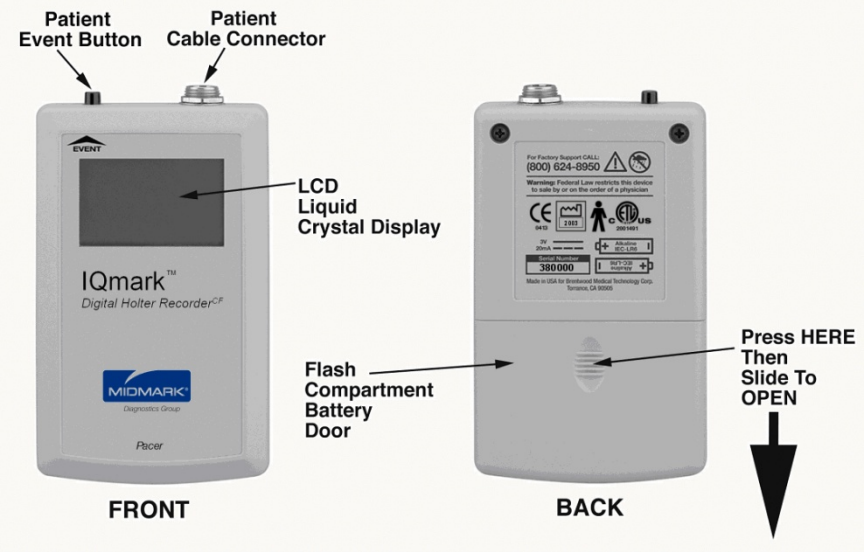


Figure 1-2 Key components

Patient Event Button

A momentary Event button is provided on the recorder as a convenient means of marking and storing event times. When Holter data is played back, ECG events are made available that correlate to the Event button being pressed.

Storage Media

The IQmark Digital Holter Recorder^{CF} utilizes a flashcard to store ECG data. The flashcard is reusable and, with proper care, should last for hundreds of recordings. The flashcard must have a memory capacity of at least 48MB. For suitable replacements or additional flashcards, please contact your Midmark sales rep or Customer Service. Always keep the flashcard away from moisture and inspect the pinholes for foreign matter prior to insertion.

When preparing for a recording session, insert the flashcard before installing the battery; it is not recommended to install the flashcard after the battery is installed, as the access port is located in the battery compartment.

B. System Specifications

IQmark Digital Holter Recorder^{CF} Performance Specifications	
Category	**Specification**
Intended Use	Provides 24-hour Holter recordings which permit the detection of abnormalities in the transmission of cardiac impulses through the heart muscle; serves as an important aid in the diagnosis of heart ailments.
PHYSICAL	
Weight	4 ounces
Dimensions	4.46 x 2.75 x 1.02 (inches) 113 x 70 x 26 (mm)
Operating Temperature	0 to 60 degrees Celsius
Non Operating Shock	1 Meter drop
Operating Position	Any orientation
Humidity	10% to 95% (non-condensing)
Storage Media	IDE/PCMCIA CompactFlash card Standard
FUNCTIONAL	
Recording Time	24-hours
Channels	3
Sample Rate	128 samples per channel/sec
Resolution	8 bits
Bandwidth	0.05 to 60Hz 3dB
Input range	5.0 mV
Battery (alkaline)	2 AA, IEC-LR6
Patient Input	5- or 7-lead configuration
CMRR	60 dB
PACE DETECTION SPECIFICATION (Serial Number 380000 or higher)	
Pulse Amplitude (at skin)	+/- 2 mV to +/- 500 mV
Pulse Width (at skin)	2ms to 0.1ms

II. Patient Preparation

A. Required Materials

Operators must have a Midmark Holter Patient Preparation Kit or a similar high quality Holter preparation kit. The Midmark Holter Patient Preparation Kit contains:

- 5 or 7 silver chloride disposable electrodes designed for 24 hour Holter monitoring
- Abrasive pad
- Patient diary
- Isopropyl alcohol wipes
- Razor
- Two (2) AA alkaline batteries

🔔 **NOTE:** Do not use 12-lead resting ECG or stress-test electrodes. We recommend using the Midmark Holter Patient Preparation Kit for consistent quality ECG data.

B. Electrode Site Preparation

Careful preparation of the patient's electrode sites is essential for obtaining an interference-free ECG and accurate result, especially in Holter monitoring. The skin is naturally a poor conductor of electricity and frequently creates artifact that distorts the ECG signal due to dry or dead epidermal cells, oils, sweat and dirt. By performing methodical skin preparation, you greatly reduce the resistive barrier that causes muscle noise and baseline wander, ensuring high-quality signal and test data.

CAUTION: Poor site preparation, improper electrode placement or use of inferior electrodes may lead to unusable data or an inaccurate analysis.

The following steps are very important in obtaining usable ECG data:

1. Select the electrode placement configuration from a reliable clinical reference source. Two typical configurations are illustrated in *Figures 2-2* and 2-*3*.

2. Select electrode sites located over bony areas where reduced tissue movement will minimize the amount of signal artifact. Electrode sites should be over a rib rather than an intercostal space.

3. Shave electrode placement areas, as needed.

4. Gently scrub the skin with an abrasive pad, lint-free gauze pad or fine sandpaper enclosed in the preparation kit. This loosens and removes dead skin.

5. Wipe the scrubbed area with a clean alcohol pad and ensure the entire electrode site is free of oil. Repeat for all sites. Allow these areas to air dry naturally before attaching electrodes.

6. Follow the electrode manufacturer's application instructions when applying snap leads to the electrodes. To simplify this process, first apply the lead wire snaps to the electrodes then apply the electrodes to the patient.

7. Remove the backing from a pre-gelled disposable electrode and place an electrode on each of the prepared electrode sites, make certain that the right colored lead is placed on the proper site. Ensure that the gel in the center of each electrode maintains contact with the prepared skin surface and the electrode is not wrinkled.

8. Form a stress loop with each electrode lead, then tape the loop to the skin. This reduces artifacts caused by snap rotation when leads are pulled or tugged by normal patient movements.

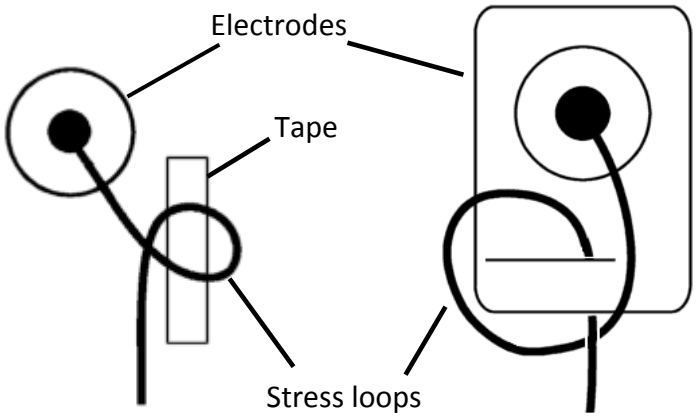


Figure 2-1 Examples of stress loops

C. Three Channel ECG Recording

- 7-lead Holter recordings
  Utilize a bipolar lead system where there is one positive and one negative lead for each channel, plus a recorder ground.

- 5-lead Holter recordings
  Utilize a bipolar lead system that shares either positive or negative leads between the channels and a recorder ground.

Five Lead Wire Configuration

Lead Color	Placement
Red	Channel 1 (-), Channel 2 (-) Place at center of manubrium and top of sternum.
White	Channel 3 (-) Place on the right side, below the V1 or V3R position, at the bottom of the rib cage.
Brown	Channel 1 (+) Place on the left side on a rib at the V3 position.
Black	Channel 2 (+), Channel 3 (+) Place on the left side at the V5 position, on a rib.
Green	Ground Place on right side opposite V5 position, i.e. V5R.

NOTE:

RED	(-)	BROWN	(+)	=	CHANNEL 1
RED	(-)	BLACK	(+)	=	CHANNEL 2
WHITE	(-)	BLACK	(+)	=	CHANNEL 3

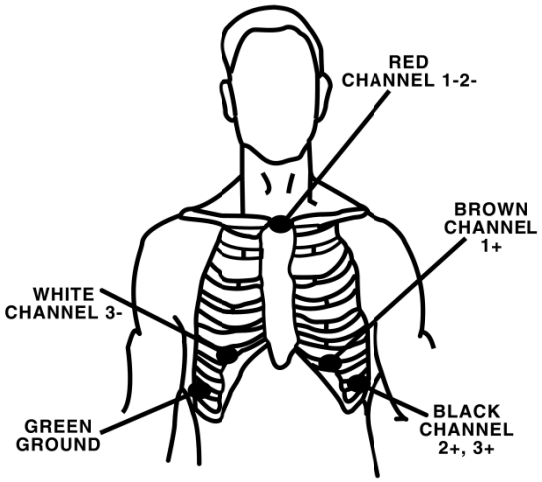


Figure 2-2 ***Typical three channel five lead electrode placement configuration***

Seven Lead Wire Configuration

Lead Color	Placement
White	Channel 1 (-) Place at top of sternum.
Red	Channel 1 (+) Place on the left side at the V_3 position, on a rib.
Black	Channel 2 (-) Place at top of sternum, adjacent to white lead.
Brown	Channel 2 (+) Place on the left side at the V_5 position, on a rib.
Blue	Channel 3 (-) Place at top of sternum, adjacent to white lead
Orange	Channel 3 (+) Place on the right side at the V_1 or V3R position, on a rib.
Green	Ground Place on the right side opposite V_5 position, i.e. V5R.

NOTE:

WHITE	(-)	RED	(+)	=	CHANNEL 1
BLACK	(-)	BROWN	(+)	=	CHANNEL 2
BLUE	(-)	ORANGE	(+)	=	CHANNEL 3

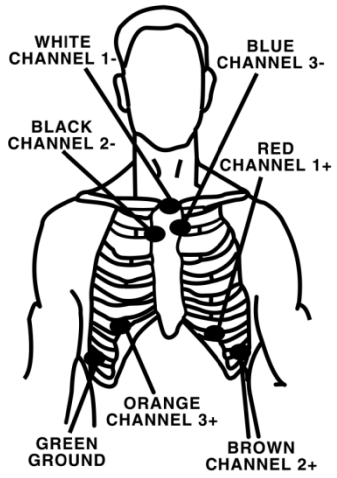


Figure 2-3 Typical three channel, seven lead electrode placement configuration

III. Recorder Operation

A. Required Materials

- One (1) Delkin® or one (1) Sandisk® CompactFlash memory card (64MB - 1GB)
- Midmark Holter Patient Preparation Kit
- IQmark Digital Holter Recorder^{CF}
- Patient cable
- Carrying case and belt

B. Recorder Set-Up and Configuration

Patient Cable

1. Remove the color-coded patient cable from the shipping package.

2. Attach cable to the patient cable connector on the recorder.
   a) Ensure proper alignment of the connector before tightening the cable to the recorder.
   b) Do not over-tighten.

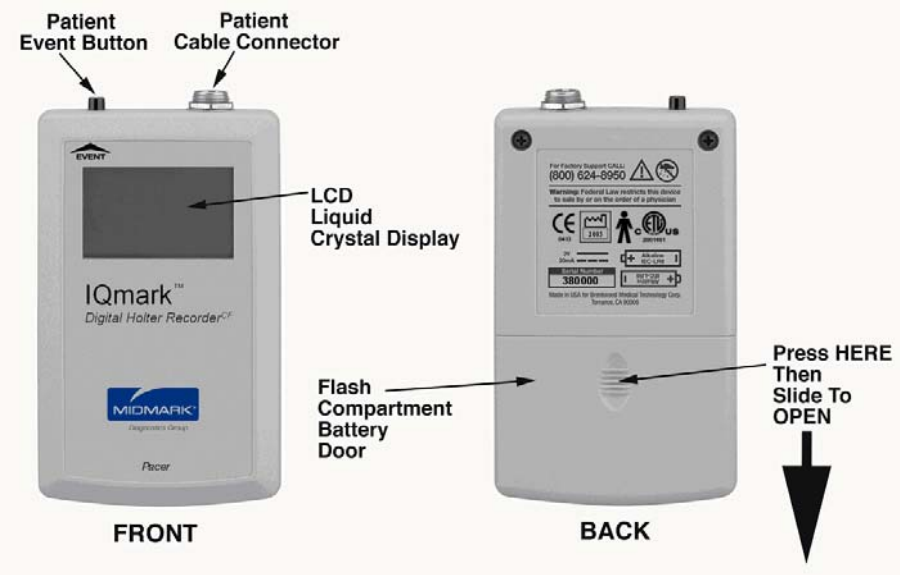


Figure 3-1 IQmark Digital Holter RecorderCF components

Recorder input configuration is automatically selected by the attachment of the appropriate patient cable. The options are 5-lead/3-channel or 7-lead/3-channel. Please see *Figures 2-2 and 2-3* for proper cable selection.

CompactFlash Card Insertion and Removal

The flashcard access port is located in the battery compartment. When the flashcard is fully inserted, the ejector button will fully extend.

Remove the flashcard by depressing the ejector button.

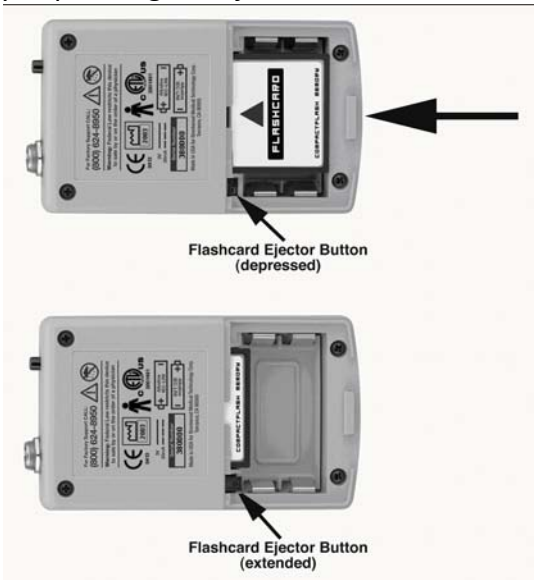


Figure 3-2 IQmark Digital Holter RecorderCF CompactFlash Card insertion/removal

C. Starting a Recording

1. Prepare the patient as described in *Section II, Patient Preparation*.

2. Inspect patient cable for signs of wear. Ensure the patient cable is properly connected to the patient input connector on the recorder.

3. Insert the flashcard (see Section *III-B, CompactFlash Card Insertion and Removal*).

   CAUTION: All previously recorded ECG data stored on the flashcard will be erased once the new battery is installed.

4. Install new alkaline AA batteries.

   NOTE: The recorder emits a continual tone and the LCD displays FLASHCARD NOT INSERTED if the flashcard is inserted improperly.

   NOTE: The recorder sounds warning beeps and displays LOW BATTERY if the power level is low. Replace the batteries immediately.

Recorder should beep once and the LCD will activate. If not, verify if:

- The above sequence was followed
- The batteries were correctly installed
- The recorder is operating properly

5. To verify connection, the recorder displays the three channels of the patient's ECG on the LCD readout. Press the event button to display an enlarged single-channel display or to rotate through the channels: All, 1, 2, 3.

6. The recorder will automatically start recording in approximately eight (8) minutes. If you need more time to complete or correct the patient connection, remove one of the batteries and replace it when you are ready to continue.

   🔔 **NOTE:** After a good connection has been verified, the ECG recording mode may be started immediately by pressing and holding the event button for five seconds or until the ECG display turns off.

7. Document the recording start time in the patient diary, preferably using the patient's watch for the correct time. Otherwise, use your own watch or a wall clock.

   🔔 **NOTE**: The recorder will always report a start time of 00:00:00. The Holter scanning technician uses the start time that is entered in the diary as the start time for the recording.

8. Before the patient is released, verify that s/he understands the following:
   - How to use the event button and patient diary (see Section *I-A, Patient Event Button* for more information).
   - Keep the recorder away from moisture.
   - Do not tamper with the recorder or remove the flashcard or batteries.
   - Avoid touching the electrode sites.
   - Do not to use an electric blanket while using the recorder.
   - Avoid environments that have strong electrical or electromagnetic interference. *See Section VI, EMC Requirements for the IQmark Digital Holter Recorder^{CF}.*

9. Place the recorder into the pouch and secure the pouch to the patient's belt via use the belt provided or through the loop on the back of the pouch.

D. Early Termination of Recording

The recorder automatically terminates each recording after 24-hours. To terminate the recording sooner, remove the battery and flashcard. A loss of up to six (6) minutes of data is normal if the recording is terminated early.

CAUTION: Removal of the flashcard during the first ten (10) minutes of recording will result in a flashcard with no data stored on it.

IV. Troubleshooting Guide

This *Troubleshooting Guide* provides a list of solutions and recommendations to potential problems you may encounter while using the IQmark Digital Holter Recorder^{CF}. Before calling Midmark Customer Service, please refer to the following table for help.

Troubleshooting Guide	
Error Message/Problem	**Potential Solution/Recommendation**
No tone or display following initial battery installation	• Batteries are very weak • Batteries are incorrectly installed
LCD displays 'FLASHCARD NOT INSERTED' and the unit emits a continuous tone following battery installation.	Incomplete flashcard installation: 1. Remove batteries 2. Install flashcard 3. Reinstall batteries
Unit emits a continuous two-tone alarm and displays 'FLASHCARD DID NOT RESET.'	• Non-supported flashcard installed • The flashcard did not initialize correctly, reinstall batteries
Unit emits a continuous single-tone beeping alarm	• The flashcard did not initialize correctly, reinstall batteries
One or more channel has low amplitude, excessive artifact or a wandering baseline.	• Bad lead wire set • Poor connection
ECG data is not observed after recording session is complete.	• Poor batteries • Unit operated for less than ten minutes prior to battery or flashcard removal • The flashcard or recorder has malfunctioned

V. Maintenance and Storage

A. Preventative Inspection

Perform a periodic preventative inspection prior to each use of the recorder. This is done to verify there is no visible damage to the recorder that may cause it to malfunction.

Visual inspection should include the inspection of the Holter recorder and all cables for signs of damage and deterioration, including but not limited to: cracks, cuts, discoloration and oxidation. If a cable or other accessory exhibits any of these symptoms replace it immediately prior to use of the recorder.

B. Cleaning the Recorder

CAUTION

Do not use aromatic hydrocarbons, rubbing alcohol or chlorinated solvents for cleaning the Holter recorder. Do not use alcohol or acetone on lead wires or cables, since they could stiffen and crack the insulating plastic.

Clean the outside of the Holter recorder with a soft cloth dampened with a mild household cleaner. Avoid using excessive amounts of solution, which may infiltrate the connectors, battery compartments or recording module. **Verify that all equipment, including accessories, are completely dry before using.**

CAUTION: Do not immerse the Holter recorder in any kind of liquid.

Cleaning the Carrying Case

If the carrying case becomes soiled, the operator has the option to purchase a new pouch or wash the existing one in cold water with a mild detergent.

Cleaning the Patient Cable

Clean the cables following a hospital approved cleaning procedure, such as those recommended by AAMI or AORN. Wiping the cables with a solution of soap and water followed by a rinse with water is a simple yet effective method for cleaning the cables.

Do not immerse the cables in water. The cables may be disinfected by wiping with a 1:10 solution of chlorine bleach and water, or a 2% gluteraldehyde solution such as Cidex ™. The cables should then be rinsed and wiped dry.

NOTE: Worn or damaged patient cables are the most common cause of poor quality recordings. Successive poor ECG tracings may indicate the patient cable needs to be replaced.

C. Bad Weather Conditions

In rain or snow conditions, instruct patients to protect the recorder from the elements by wearing the recorder inside a coat.

D. Storage

To prevent damage to the recorder due to battery leakage or oxidation, the batteries should be removed whenever the recorder is not in use or prior to storage for a long period of time. Avoid extreme humidity and heat during storage.

Although the flashcard is very durable, it should be stored within the recorder or its original case when not in use. This reduces the possibility of dust or moisture damaging the flashcard.

E. Radio and Television Interference

This equipment generates and uses radio frequency energy. If not installed and used properly, in strict accordance with the manufacturer's instructions, it may cause interference with radio and television reception.

This equipment has been tested and proven to be in compliance with standards for medical devices in accordance with the IEC 601-1 rules, which are designed to provide reasonable protection against such interference in a medical or hospital environment. See *Section VI, EMC Requirements for the IQmark Digital Holter Recorder^{CF}* for requirements when operating the recorder.

VI. EMC Requirements for the IQmark Digital Holter Recorder^{CF}

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Addendum.
Portable and mobile RF communications equipment can affect the operation of medical electrical equipment. The IQmark Digital Holter Recorder^{CF} is medical electrical equipment.

The following is a list of the lead wires and CompactFlash cards that are used as part of the IQmark Digital Holter Recorder^{CF} that comply with sections 36.201 and 36.202 of the EMC Standard IEC60601-1-2 (E). Electromagnetic compatibility testing has not been conducted using lead wires longer than 40 inches (101.6 cm).

Lead Wires
5-Lead 3-Channel Lead Wires
7-Lead 3-Channel Lead Wires

Memory Cards
SanDisk CompactFlash card: standard length, Type I CompactFlash cards conforming to CompactFlash Specification 1.4 as issued by the CompactFlash Association.

Use of lead wires, CompactFlash cards, or accessories other than those specified, with the exception of lead wires, CompactFlash cards, and accessories sold by the manufacturer of the IQmark Digital Holter Recorder^{CF} as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the IQmark Digital Holter Recorder^{CF}.

CAUTION: THE IQMARK DIGITAL HOLTER RECORDER^{CF} SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF ADJACENT OR STACKED USE IS NECESSARY, THE IQMARK DIGITAL HOLTER RECORDER^{CF} SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</td></tr>
<tr><td colspan="3">The IQmark Digital Holter Recorder^{CF} is intended for use in the electromagnetic environment specified below. The customer or the user of the IQmark Digital Holter Recorder^{CF} should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR11</td><td>Group 1</td><td>The IQmark Digital Holter Recorder^{CF} uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR11</td><td>Class B</td><td rowspan="3">The IQmark Digital Holter Recorder^{CF} is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
CISPR11</td><td>N/A</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>N/A</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity			
The IQmark Digital Holter Recorder^{CF} is intended for use in the electromagnetic environment specified below. The customer or the user of the IQmark Digital Holter Recorder^{CF} should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Battery-powered device
Surge IEC 61000-4-5	±1 kV for differential mode ±2 kV common mode	N/A	Battery-powered device
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	N/A	Battery-powered device
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE—U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

The IQmark Digital Holter Recorder^{CF} is intended for use in the electromagnetic environment specified below. The customer or the user of the IQmark Digital Holter Recorder^{CF} should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the IQmark Digital Holter Recorder^{CF}, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[V1] V N/A	**Recommended separation distance**
Radiated RF IEC 6100-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Not Applicable d = 1.2 √*P* 80 MHz to 800 MHz d = 2.3 √*P* 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of equipment marked with the following symbol: of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the IQmark Digital Holter Recorder^{CF} is used exceeds the applicable RF compliance level above, the IQmark Digital Holter Recorder^{CF} should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the IQmark Digital Holter Recorder^{CF}

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [*V*1] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the IQmark Digital Holter Recorder^{CF}

The IQmark Digital Holter Recorder^{CF} is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IQmark Digital Holter Recorder^{CF} can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IQmark Digital Holter Recorder^{CF} as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** **d = 1.2 √*P***	**800 MHz to 2.5 GHz** **d = 2.3 √*P***
0.01	N/A	0.12	0.23
0.1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

VII. Service and Support

The IQmark Digital Holter Recorder^{CF} does not contain user serviceable components. Please return to Midmark for servicing.

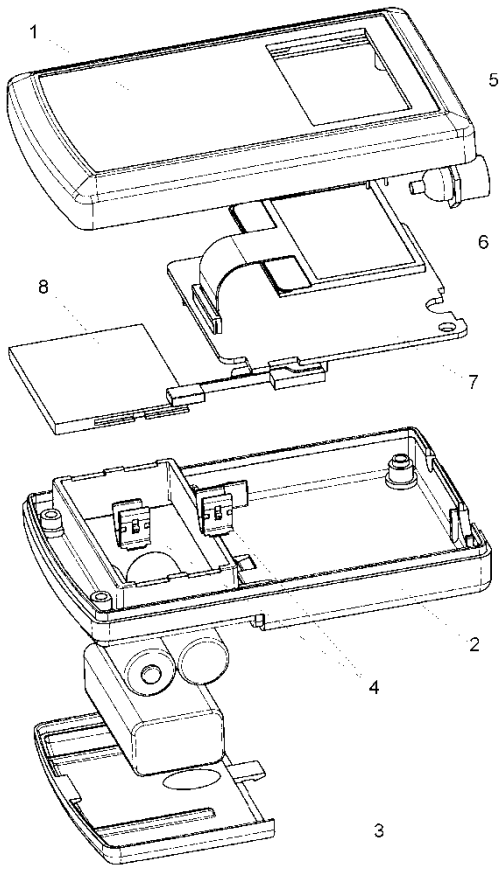


Figure 7-1 Expanded View of IQmark Digital Holter Recorder^{CF}

Legend

01).....	Top cover
02).....	Bottom cover
03).....	Battery cover
04).....	Battery clips (4)
05).....	Patient connector bulkhead
06).....	Liquid crystal display (LCD)
07).....	Printed circuit board (PCB)
08).....	CompactFlash card

A. Technical Support

For questions pertaining to this product and technical support, consult this manual, the *Troubleshooting Guide* or contact Midmark Support Services at (800) 624-8950, ext. 2 between 6:30 AM to 4:30 PM, Pacific Standard Time.

B. Limited Warranty

All Midmark digital module products are warranted to be free from manufacturing and material defects for 12 months from the date of purchase; CompactFlash cards are warranted for 90 days and Holter patient cables are warranted for 30 days. Any misuse or abuse of a Midmark product voids all applicable warranties. A full copy of the Midmark limited warranty is found on the warranty registration documentation provided with this product.

Return Materials Authorization (RMA)

To return any product for any reason, a Return Materials Authorization (RMA) number must be obtained from a Midmark Support Services representative. The number must be referenced on the package(s) containing the items to be returned, and in any correspondence regarding the return.

Shipping

Before shipping any unit to Midmark, be certain that an RMA number has been issued and that all guidelines regarding this authorization are followed.

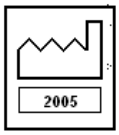
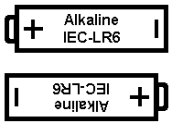
We highly recommend that you follow all guidelines for the shipment of medical products set forth by your shipping company. If you have a question regarding the appropriate shipment method, please feel free to ask when calling for your RMA number. It is ultimately the responsibility of the customer when shipping a product to ensure that all packages and their contents arrive at Midmark safely.

MIDMARK WILL NOT ASSUME RESPONSIBILITY FOR DAMAGE INCURRED BY IMPROPER PACKAGING, SHIPMENT OR PRODUCT USE. SUCH ACTIONS VOID ALL APPLICABLE WARRANTIES.

Midmark Diagnostics Group
1125 West 190th Street
Gardena, CA 90248
Tel: (310) 516-6050
USA: (800) 624-8950, ext. 2
Fax:(310) 516-6517

C. Safety and International Symbols

The following symbols are used on the IQmark Digital Holter Recorder^{CF} product. Refer to this directory for details concerning symbols used on the instrument.

Symbol	Description
	ATTENTION Refer to manual for instructions
	Year of manufacture
	Battery Orientation This device uses 2 AA alkaline batteries. The icon indicates the proper orientation of batteries to be installed.
	DC Voltage This device uses 3-Volt DC power and consumes 20mA (nominal) when in use.
	CE Mark Equipment displaying this symbol has passed specific safety tests and adheres to international quality standards established by the European Commission.
	Device is compliant with IEC 60601-1 as a Type BF, internally powered device.
	“Ordinary” enclosure IPX0: Keep the instrument away from splashing water.
	Conforms to UL Std. 2601-1 and Certified to CAN/CSA Std. C22.2 No. 601.1.

VIII. Reordering Supplies

Contact your local distributor for reordering supplies for your Holter monitoring.

Midmark Part Number	Description
1-370-0002	CompactFlash card
2-100-0080	Prep Kit – IQmark Holter, 5-lead, 2AA's (each)
2-100-0081	Prep Kit – IQmark Holter, 5-lead, 2AA's (case – 30 kits)
2-100-0090	Prep Kit – IQmark Holter, 7-lead, 2AA's (each)
2-100-0091	Prep Kit – IQmark Holter, 7-lead, 2AA's (case – 30 kits)
3-370-0001	Lead Wire, 5-lead, IQmark Digital Recorder^{CF}
3-370-0002	Lead Wire, 7-lead, IQmark Digital Recorder^{CF}
3-370-0003	Pouch with Belt for IQmark Digital Recorder^{CF}

Midmark Diagnostics Group
1125 W. 190th Street
Gardena, California 90248
Support Services: 1-800-624-8950, Option 2
www.midmark.com
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